

REMARKS

Claims 1, 3-13, 18 and 19 are pending.

The replacement of "gene" with "substantially purified nucleic acid" in claim 1 is inherently supported by the specification at page 10, lines 11-23 and page 33, lines 15-17. The Examiner suggested a recitation of "isolated and purified nucleic acid".

Applicants respectfully note that "isolated" and "purified" appeared to be redundant and that any nucleic acid that has been isolated or purified with a known method is most likely only substantially purified because many known isolation or purification procedures for nucleic acids do not guarantee getting a nucleic acid that is 100% pure.

The replacement of "biological cell-control agent" with "composition" and the recitation of the "carrier" in claims 7-12 are supported by the specification at page 17, line 17 and page 32, lines 16-23.

Applicants submit that the amendment to the body of claim 1 would not narrow the scope of the amended claim limitation because the amendment involves deletion of the molecular weight limitation and the limitation regarding the C terminal. The amendment to the preambles of claims 1 and 3 also would not narrow the scopes of claims 1 and 3 because a nucleic acid encoding the pentapeptide should be no narrower than the "gene" encoding the same pentapeptide.

Applicants also submit that the amendment to claims 7-12 would not narrow the scope of the amended claim limitation because the ineffective component of a "biological cell-control agent" necessarily must be physiologically acceptable.

The amendment to claim 13 would not narrow the scope of the claim because claim 13 is drawn to the pentapeptide of SEQ ID NO:1 regardless of the amendment.

Sequence Listing

A second substitute sequence listing was filed on July 8, 2003 in compliance with 37 CFR 1.821. Withdrawal of the objection related to the sequence listing is requested.

Claim Rejection under 35 U.S.C. 112, First Paragraph

Claims 1-3 were rejected as failing to comply with the written description requirement because of the recitation "gene." Applicants respectfully traverse the rejection. The word "gene" has been replaced with "substantially purified nucleic acid" similar to the Examiner's suggestion of "isolated and purified nucleic acid" as explained above. Withdrawal of the rejection is requested.

Claims 7-12 and 14-17 were rejected because the Examiner asserted that the specification fails to show that any agent containing the pentapeptide or tetrapeptide of the present invention is indeed effective in treating cancer. Applicants respectfully traverse the rejection because applicants submit that the *in vitro* data presented in the specification would reasonably lead a person skilled in the art to conclude that the pentapeptide or tetrapeptide of the present invention would be effective in treating cancer since *in vitro* data on cancer cells have been accepted as reasonably predictive for the effectiveness in cancer treatment and have been routinely used in the art to screen for anti-cancer agents. In addition, the nonenablement rejection should be withdrawn because the court held that data showing the effect of a chemical against cancer cells *in vitro* were sufficient in enabling a method of using the chemical to treat cancer, *In re Brana*, 34 USPQ2d 1436 (CAFC, 1995). In the present application, the

pentapeptide and tetrapeptide were shown to be effective in inhibiting the growth of rat hepatoma cells *in vitro* (see Examples 9 and 10 in pages 49-52).

Withdrawal of the written description rejection and non-enablement rejection is requested.

Claim Rejection under 35 U.S.C. 112, Second Paragraph

Claims 1-3 were rejected as vague because of the recitation "gene". Applicants respectfully traverse the rejection. By replacing "gene" with "substantially purified nucleic acid" (similar to the Examiner's suggestion), applicants submit that claims 1 and 3 should not be rejected as vague.

Claims 3 and 5 were rejected as vague because the Examiner asserted that "derived from pre-larvae" was indefinite. Applicants respectfully traverse the rejection. With the replacement of "derived" with "obtained" in claims 3 and 5, applicants submit that claims 3 and 5 should not be rejected as vague.

Withdrawal of the indefiniteness rejections is requested.

Allowed Claims

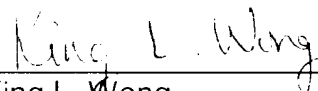
Applicants thank the Examiner for allowing claims 4, 6 and 13. Claims 18 and 19, drawn toward the tetrapeptides ILRG-COOH and ILRG-NH₂, respectively, have been added. Since the Examiner stated that SEQ ID NO:2 is free of prior art, applicants submit that claims 18 and 19 should also be free of prior art.

Conclusion

In view of the above reasoning, applicants submit that the application is in a condition for allowance. A Notice of Allowance is believed in order.

In the event that the filing of this paper is not deemed timely, Applicants petition for an appropriate extension of time. Any petition fee for the extension of time and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 01-2300, referencing Docket No. 026390-00001.

Respectfully submitted,



King L. Wong
Registration No. 37,500

Customer No. 004372
ARENT FOX KINTNER PLOTKIN & KAHN, PLLC
1050 Connecticut Avenue, N.W.,
Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 638-4810

Enclosure: Petition for Extension of Time
Amendment and Fee Transmittal

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